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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,464	02/07/2002	Gregory R. Collins	1508/1124US1	1828

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DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/072,464	Applicant(s) COLLINS ET AL.	
	Examiner John Kim	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-36 and 38-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-46 is/are allowed.
- 6) ☒ Claim(s) 2-6, 18, 27 and 29 is/are rejected.
- 7) ☒ Claim(s) 7-17, 19-26, 28 and 30-36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 27 and 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of "the prescribed criteria" in claims 27 and 29 lack positive antecedent basis.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2, 5 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application No. 0526152 A1 (hereinafter referred to as EP '152). EP '152 teaches a hemodiafiltration system comprising a first conduit (6) having a first end and an opposing second end, the first end receiving first fluid from dialysis machine and the second end for discharging dialysate fluid to a dialyzer (2) and a second conduit (8) in selective communication with the first conduit (6) to divert amount of first fluid from the first conduit (6) through at least one sterilizing filter (27) via a pump (14) to produce a substitution fluid and control unit (21) responsive to flow rate of first fluid and a returning fluid in duct (7) (see figure 1; page 2, line 56 – page 4, line 46).
5. Claims 2-3, 5, 6 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 00/06292. WO 00/06292 teaches a hemodiafiltration method and system comprising a first conduit (41) having a first end and an opposing second end, the first end receiving first fluid

from dialysis machine (43) and the second end for discharging dialysate fluid to a dialyzer (22) and second conduit (2) in selective communication with the first conduit (41) to divert amount of first fluid from the first conduit (41) through at least one sterilizing filter (11, 13) via a substitution fluid pump (8) to produce a substitution fluid and control unit (40) responsive to flow rate of diverted first fluid via a flow meter (10) and a flow rate of blood via a flow meter (26) to control a substitution fluid pump (8) wherein the control unit (40) also receives signals from pressure sensors (9, 132) which are located upstream and downstream of substitution fluid pump (8) in the second conduit (2) (see figure 1; page 3, lines 19-21; page 7, line 7 – page 12, line 25).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/06292 as applied to claim 2 above, and further in view of U.S. Patent No. 6,284,141 (hereinafter referred to as Shaldon et al). WO 00/06292 teaches a hemodiafiltration system as described in above paragraph 5. Claim 4 essentially differs from the apparatus of WO 00/06292 in reciting a first flow meter disposed within the first conduit for detecting a flow rate of one of the first fluid and the dialysate fluid and in communication with the control unit. Shaldon et al teach a hemodiafiltration apparatus comprising a first flow meter (10) disposed within the first conduit for detecting a flow rate of one of the first fluid and the dialysate fluid and in communication with the control unit (14) and a second conduit (16) in selective communication with the first

conduit and having a pump (17) for providing a substitution fluid to an extracorporeal circuit (see figure 5; col. 7, line 18 – col. 8, line 35). Shaldon et al teach that signal from the flow meter (10) and other inputs are fed to a control unit (14) for determining efficiency (see col. 7, lines 18-57). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate a first flow meter disposed within the first conduit of WO 00/06292 for detecting a flow rate of dialysate fluid and determining efficiency as suggested by Shaldon et al.

8. Claims 27 and 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Claims 7-17, 19-26, 28 and 30-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 38-46 are allowed.

11. Applicant's arguments with respect to claims 3-36 and 38-46 have been considered but are moot in view of the new ground(s) of rejection. Applicants argue that the claimed first characteristic is a flow rate of one of the fluids that flows within the first conduit that extends between the dialysis machine and the dialyzer. However, applicants did not explicitly claim that the flow rate is one that flows within the first conduit in claim 2.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,280,632 and 6,039,877 and 6,139,748 and 6,406,631 and 6,423,231 and US 2002/0023879 teach hemodiafiltration apparatuses.

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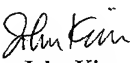
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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
November 12, 2003